

...1.1. March ... 2025

Mr Rakesh Bamzai Chief Executive Officer & Managing Director Mylan Laboratories Limited Plot No 564/A/22 Road No 92 Jubilee Hills Hyderabad – 500096 India

Dear Mr Bamzai

### **RE:** Side Letter re obligations of Mylan Laboratories Limited

We refer to the Licence Agreement between ViiV Healthcare Company ("ViiV") and The Medicines Patent Pool Foundation ("MPPF") executed on 23 July 2022 ("the Head Licence") and the Sublicence Agreement between MPPF and Mylan Laboratories Limited ("Mylan") dated 28 March 2023 ("the **Sublicence**"), to enable broad access in resource-limited countries to the Licensed Product (as defined in the Sublicence) to reduce the risk of HIV-1 infection in persons (weighing at least 35kg) at risk of acquiring HIV-1.

#### Background

Pursuant to Clause 3 of the Sublicence, Mylan will be granted the right to, either by itself or through an 'Approved Affiliate', manufacture the Licensed Product solely for use in the Field in the Permitted Market, as defined in the Sublicence, among other things.

Mylan has divested on 3 June 2024 its API business to a third-party company, Tianish Laboratories Limited ("**Tianish**").

Mylan now wishes to procure Compound manufactured by Tianish for use in its manufacture of the Licensed Product . However, Tianish cannot be an Approved Affiliate as it is not directly or indirectly controlled by Mylan and is a separate corporate entity that is outside of Mylan's corporate group.

In this regard, MPPF and ViiV agree to allow Tianish to manufacture the Compound solely for supply to Mylan notwithstanding that the Sublicence only permits Mylan or its Approved Affiliate to manufacture the Licensed Product. Mylan confirms that it will only procure Compound manufactured by Tianish with respect to its formulation of the Licensed Product.

Separately, in July 2022, Mylan received an overall ECOVADIS score below the expected minimum of 45 in relation to its environmental, labour and human rights, ethics and sustainable procurement policies and practices ("**ECOVADIS Score**"). As Mylan is divesting those manufacturing facilities to Tianish, it is expected that Mylan will procure that Tianish will use its best endeavours to improve the ECOVADIS Score in respect of those manufacturing facilities.

In light of the above, MPPF and ViiV agree that the granting of the Sublicence is conditional on Mylan agreeing to the terms set out in this Side Letter.

#### Terms

Under this Side Letter, MPPF, ViiV and Mylan agree to the terms below. Hereafter, all capitalised terms below shall have the same meaning as in the Sublicence unless otherwise defined.

### 1. Tianish manufacturing

1.1. Notwithstanding the licence granted under Clause 3 of the Sublicence being non-sublicensable other than to an Approved Affiliate with respect to the manufacturing of the Licensed Product,

\_advancing innovation, access and public health\_

MPPF approves for Mylan to have the right to grant a sublicence of the Patent Rights to Tianish, to the extent necessary, for Tianish to manufacture the Compound solely for supply to Mylan.

Mylan shall:

- (a) ensure that Tianish complies with all applicable terms of the Sublicence as if it was Mylan under that Sublicence;
- (b) not permit Tianish to sub-contract or assign any part of the manufacturing of the Compound without the prior written approval of MPPF and ViiV; and
- (c) be liable for the acts and omissions of Tianish as if such acts and/or omissions were the acts and/or omissions of Mylan.
- 1.2. In the event Tianish fails to comply with any terms of the Sublicence, MPPF shall have the right to withdraw its approval under Clause 1.1 above with immediate effect by providing written notice to Mylan.
- 1.3. In the event that Tianish is acquired by a third party, Mylan acknowledges and accepts that the acquisition of Tianish by a third party would be considered a change in control pursuant to Clause 21.4.4 of the Sublicence and gives MPPF the right to terminate the Sublicence.
- 1.4. Mylan agrees that it will only procure the Compound from Tianish for use in Mylan's manufacturing of the Licensed Product.

## 2. ECOVADIS conditions

- 2.1. Mylan shall require that Tianish undertakes, in a written agreement between Tianish and Mylan, to:
  - use its best efforts to engage in any reasonable activities to improve the ECOVADIS Scores covering the facilities involved in the manufacture of the Compound to an ECOVADIS Score of a minimum of 45 or above ("ECOVADIS Activities");
  - (b) without limitation to (a) above, no later than three months from the date on which Mylan signs this side letter ("Side Letter Effective Date"), share with MPPF a detailed action plan setting out the ECOVADIS Activities that it will perform, including the timeline for the completion of such activities ("ECOVADIS Action Plan"). Mylan will assist Tianish in sharing the ECOVADIS Action Plan with MPPF, as necessary;
  - (c) with respect to the ECOVADIS Action Plan:
    - (i) in advance of each Quarterly Meeting, provide Mylan with an update on its progress on the ECOVADIS Action Plan and, if requested by MPPF, to attend the Quarterly Meeting to review and discuss with MPPF progress on the ECOVADIS Action Plan and agree with MPPF to any necessary amendments to the ECOVADIS Action Plan. Mylan will share Tianish's progress updates with MPPF at the Quarterly Meeting and shall assist MPPF in arranging Tianish's attendance at the Quarterly Meeting, if requested; and
    - (ii) upon the request of MPPF, permit and allow MPPF's representatives to visit and inspect Tianish's facilities involved in the manufacture of the Compound for the purpose of evaluating Tianish's performance of the ECOVADIS Action Plan. Mylan will assist MPPF in scheduling such visits with Tianish, and MPPF shall comply with all local rules and policies during each visit.
- 2.2. Within three years from the Side Letter Effective Date:
  - (a) to the extent Tianish has not achieved an ECOVADIS Score covering the facilities involved in the manufacture of the Compound to a minimum of 45 or aboveMylan acknowledges that MPPF has the right to audit Mylan for compliance with the Sublicence pursuant to Clause 19.2 of Sublicence, including but not limited to compliance with Clause 20 of the Sublicence;
  - (b) Mylan shall require Tianish to undertake, in a written agreement between Tianish and Mylan, to provide any assistance, information, or documentation reasonably required in connection with said audit; and

(c) without limiting MPPF's rights under the Sublicence, if the audit reveals a breach of Clause 20 of the Sublicence, Mylan shall promptly take corrective actions in relation to the identified non-compliance, including by procuring that Tianish take any necessary corrective actions and agree with MPPF to any necessary amendments to the ECOVADIS Action Plan, failing which MPPF reserves all its rights under the Sublicence.

This Side Letter will be governed by the terms of Clause 34 (Governing Law and Dispute Resolution) of the Sublicence, and ViiV shall have such Third Party Rights under this Side Letter as agreed pursuant to Clause 24 (Third Party Rights) of the Sublicence. The parties intend this Side Letter to be legally binding.

Please acknowledge receipt and acceptance of this Side Letter by signing and returning a copy of this Side Letter.

Yours sincerely

**Medicines Patent Pool Foundation** 

DocuSigned by: Charles Gore

Charles Gore Executive Director

# ViiV Healthcare Company

Instal Baker

Crystal Baker Vice President, ViiV Company Secretary, North America

We hereby acknowledge receipt and accept the contents of this Side Letter

# **Mylan Laboratories Limited**

Arvind Kanda Digitally signed by Arvind Kanda Date: 2025.06.27 19:58:10 +05'30'

Name: Arvind Kanda Position: Head of India & Access Markets (ARV, India, SA and SSA) Date: 27 June 2025